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BISSETT, MELANIE D

ART UNIT	PAPER NUMBER
1711	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,636	SMITH ET AL.	
	Examiner	Art Unit	
	Melanie D. Bissett	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-60 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-60 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 10/19/01 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: parts 10, 12, 14, and 16. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Summary of the Independent Claims

2. Claim 1 is drawn to a multiple layer structure having a modulus of elasticity of less than about 60,000 psi, the structure comprising a first polyester or polyamide layer and a second layer attached to the first layer, where the second layer is an ethylene/α-olefin copolymer having a density of less than about 0.900 g/cc. The claim also cites an intended use for fabricating a flexible container or tank liner. Claim 18 is drawn to a multi-layered structure having a modulus of elasticity of less than about 60,000 psi, the structure comprising a first PCCE layer and a second layer attached to the first layer, where the second layer is an ethylene/α-olefin copolymer having a density of less than about 0.900 g/cc. The claim also limits layer thicknesses and cites an intended use for fabricating a flexible container or tank liner. Claim 29 is drawn to a multi-layered structure having a modulus of elasticity of less than about 60,000 psi, the structure comprising a first PCCE layer, a second layer attached to the first layer, and a tie layer between the first and second layers, where the second layer is an ethylene/α-olefin

copolymer having a density of less than about 0.900 g/cc. The claim also limits layer thicknesses and cites an intended use for fabricating medical products. Claim 39 is drawn to a method for fabricating a multi-layered structure comprising providing a PCCE material, providing an ethylene/α-olefin copolymer having a density of less than about 0.900 g/cc, providing a tie material, and co-extruding the materials such that the tie layer attaches the first and second layers without the use of slip agents. Claim 46 is drawn to a multi-layered structure having a modulus of elasticity of less than about 60,000 psi, the structure comprising a first polyamide layer and a second layer attached to the first layer, where the second layer is an ethylene/α-olefin copolymer having a density of less than about 0.900 g/cc. The claim also limits layer thicknesses and cites an intended use for fabricating medical products.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3, 6-10, 14-17, 46-49, 53-56, and 59-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenbaum et al. as evidenced by Piper et al.

5. Rosenbaum discloses a multi-layered structure for medical articles and containers, where the structure contains a skin layer, a barrier layer, and an RF layer (abstract; col. 3 lines 56-62). A core layer between the skin and RF layers comprises Tafmer™ ultra low density polyethylene (ULDPE) (col. 4 lines 48-57), a material noted by the applicant as an ethylene/α-olefin having a C_{4-8} α-olefin. Piper teaches Tafmer™ ULDPE as prepared using a single-site catalyst (col. 6 lines 42-56). Suitable barrier layers include polyamide materials, which may be attached between the skin and RF layers by a tie layer (col. 5 lines 3-22). RF layers may also comprise ULDPE, having a density less than 0.90 g/cc (col. 6 lines 62-66). RF layers may also comprise polyamides, preferably those resulting from a reaction of dimer fatty acids (col. 8 lines 12-35). Suitable tie layers include those cited by the applicant as modified polyolefin blends (col. 9 line 65-col. 10 line 4). Figure 7 shows a multi-layered article having an elastic modulus of 20 kpsi (col. 11 lines 14-17; table cols. 13-14). In this example, a 2.0-mil core layer comprising ULDPE is attached to a 5.0-mil RF layer comprising a dimer fatty acid-produced polyamide through two 0.5-mil polyolefin blend tie layers. No slip agents are mentioned in the example. The layers may be processed by co-extrusion or co-extrusion coating (col. 10 lines 40-43). The reference reports RF layers of 5-8 mils and tie layers of 0.2-1.0 mils (col. 8 lines 56-60; col. 9 line 65-col. 10 line 4).

6. Regarding the applicant's claims 2-3, it is the examiner's position that, when the limitations of claims 2-3 are read into claim 1, the first layer of claim 1 is still open to either a specific polyester *or a polyamide material*. Thus, since the reference teaches polyamide materials instead of polyester materials, claims 2-3 are still anticipated. If

claims 2-3 were rewritten to limit the first layer to a polyester material (i.e., "wherein the first layer is a polyester ether"), the rejection of claims 2-3 using Rosenbaum et al. would be withdrawn.

7. Claims 1-10, 14-15, 17, 46-49, 54, and 56-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Piper et al.

8. Piper discloses a multi-layered film comprising an outer layer and a layer containing an ethylene/α-olefin interpolymer having a density of less than about 0.91 g/cc (abstract). The materials are used to make bags for foodstuffs (col. 2 lines 28-30). The outer layer contains up to 80% of another polymer, where polyamides and polyesters are both mentioned as possible blended polymers (col. 6 lines 5-16). The second layer includes a copolymer having a density most preferably less than about 0.900 g/cc (col. 6 lines 32-36) and prepared from a single-site catalyst (col. 6 lines 42-56). The reference notes the use of 1-butene, 1-hexene, and 1-octene as α-olefins (col. 6 lines 57-63). Thicknesses range from 0.001-0.1 mm (~0.04-4 mils) (col. 7 lines 22-31), where thicknesses of 4 mils are exemplified (examples 1-3). Piper further discusses the use of additional polyamide or polyester layers, where nylon-6, nylon-10, nylon-11, nylon-12, nylon-22, and nylon-610 are all mentioned as polyamide materials (col. 8 lines 17-47). Most preferred thicknesses of the polyamide or polyester layer range from 0.05-0.25 mm (~2-10 mils) (col. 8 lines 48-56). The multi-layered films may also contain tie layers (col. 8 lines 62-63). The reference exemplifies a tie layer

thickness of 1.2 mils (examples 1-3). Films are co-extruded without the use of slip agents (examples 1-3).

9. Piper demonstrates several layer structures for the multi-layered films, many of which show a layer B (ethylene/α-olefin copolymer) attached to a layer D or D' (may be amide or ester) or attached to a layer E or E' (polyester or polyamide) (col. 9 lines 19-47). Tie layers may be used in any structure. Thus, one skilled in the art would clearly envision the use of tie layers to adhere any of the given layers. The multi-layered films have a most preferred Young's modulus above 400 MPa (58,015 psi), but the reference encompasses a lower "preferred" modulus value of 200 MPa (29,007 psi) (col. 9 line 61-col. 10 line 4). Thus, the reference teaches elastic modulus values of below 60,000 psi.

10. Regarding the intended use for fabricating medical products, the reference does not seem to mention the use of the articles in medical products. However, the articles are capable for use in food wrapping and containers. It is the examiner's position that the articles are capable of use in medical applications, lacking evidence to the contrary.

11. Regarding the applicant's claims 2-3, it is the examiner's position that, when the limitations of claims 2-3 are read into claim 1, the first layer of claim 1 is still open to either a specific polyester *or a polyamide material.* Thus, when polyamide layers are used instead of polyester layers, claims 2-3 are still anticipated. If claims 2-3 were rewritten to limit the first layer to a polyester material (i.e., "wherein the first layer is a polyester ether"), the rejection of claims 2-3 using Piper et al. would be withdrawn.

12. Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Shang et al.

13. Shang discloses polymer films for fabricating flexible medical containers [0003] having a modulus of elasticity below 60,000 psi [0040]. The reference teaches layers containing ULDPE, preferably made from a single-site catalyst and an α-olefin having 4-8 carbon atoms [0042]. Skin layers may be attached to the polyolefin film, where a preferred skin layer comprises PCCE [0089]-[0090].

14. Regarding the applicant's claims 4-7, it is the examiner's position that, when the limitations of claims 4-7 are read into claim 1, the first layer of claim 1 is still open to either a specific polyamide *or a polyester material*. Thus, when polyester layers are used instead of polyamide layers, claims 4-7 are still anticipated. If claims 4-7 were rewritten to limit the first layer to a polyamide material (excluding polyester materials; i.e., "wherein the first layer is a polyamide and is selected from"), the rejection of claims 4-7 using Shang et al. would be withdrawn.

15. Claims 1-8, 10, 14-19, 21, 25-30, 35-40, 45-47, 49, and 53-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Small, Jr. et al.

16. Small, Jr. discloses multi-layered structures for flexible medical packaging comprising an ethylene/α-olefin copolymer layer, an intermediate tie layer, and an exterior layer chosen from polyester, copolyester, polyamide, or polyolefin (col. 1 lines 39-62). The polyolefin copolymer preferably has a density in the range of 0.86-0.916 g/cc, teaching the use of copolymers having densities less than 0.900 g/cc (col. 2 lines

37-46). Preferred α-olefins include those having 3-12 carbon atoms (col. 2 lines 65-67). Preferred copolyesters include PCCE (col. 3 lines 45-54; examples 1, 3-4), and preferred polyamides include nylon-6, nylon-6,6, nylon-6,9, nylon-6,12, nylon-11, or nylon-12 (col. 4 lines 3-14). Small, Jr. teaches that the multi-layered structures may be cast co-extruded by conventional techniques to form containers, pouches, and packages for medical purposes (col. 6 lines 50-65). Examples show ethylene/α-olefin layers having a thickness of 5.7-6.8 mils, a tie layer having a thickness of 0.46-1 mils, and an exterior layer having a thickness of 0.7-1.4 mils, where the thicknesses of the layers are known to affect the autoclavability and other properties of the film (col. 2 lines 29-46). Because the reference mentions the optional addition of slip agents (col. 6 lines 42-49) and exemplifies the invention without the addition of such agents, it is the examiner's position that the reference teaches the formation of multi-layered structures without the addition of slip agents.

17. However, Small, Jr. lacks mention of the applicant's claimed elasticity modulus values. Since the materials used in Small, Jr. encompass the applicant's claimed materials of use in the invention and are similar to those exemplified by the applicant, it is the examiner's position that the films of Small, Jr.'s invention would inherently possess the applicant's claimed modulus of elasticity.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claims 10, 14-21, 25-31, 35-41, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shang et al. in view of Small, Jr. et al.

20. Shang et al. applies as above, failing to mention the thickness and use of a tie layer in the invention. Small, Jr. discloses multi-layered structures for flexible medical packaging comprising an ethylene/α-olefin copolymer layer, an intermediate tie layer, and an exterior layer chosen from polyester, copolyester, polyamide, or polyolefin (col. 1 lines 39-62). Small, Jr. teaches that the multi-layered structures may be cast co-extruded by conventional techniques to form containers, pouches, and packages for medical purposes (col. 6 lines 50-65). Examples show ethylene/α-olefin layers having a thickness of 5.7-6.8 mils, a tie layer having a thickness of 0.46-1 mils, and an exterior layer having a thickness of 0.7-1.4 mils, where the thicknesses of the layers are known to affect the autoclavability and other properties of the film (col. 2 lines 29-46). Since the multi-layered structures of Shang share a common desired application and a need to stand up to autoclave sterilization [0040], it is the examiner's position that it would have been prima facie obvious to use Small, Jr.'s teaching as a guide for choosing layer thickness values which optimize autoclavability and mechanical properties of a multi-layered film.

21. Also, Small, Jr. teaches that the use of a tie layer between the polyamide or polyester layer and the ethylene/α-olefin layer serves to improve adhesion and prevent delamination of the layers of the structure (col. 2 lines 12-17). Therefore, it is the

examiner's position that it would have been prima facie obvious to use a tie layer between the polyamide or polyester layer and the ethylene/α-olefin layer of Shang's invention to improve adhesion and prevent delamination of the multi-layered film.

22. Shang also does not seem to teach the applicant's claimed co-extrusion techniques. Small, Jr. teaches multi-layered films formed by cast co-extrusion without the use of slip agents. Because the multi-layered structures of Shang share a common layer structure and desired application, and because Small, Jr. teaches the conventionality of using such cast-coextrusion techniques, it is the examiner's position that it would have been prima facie obvious to use the cast-coextrusion technique taught by Small, Jr. without the use of slip agents in Shang's invention with the expectancy of beneficial results.

23. Claims 11-13 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenbaum et al. in view of Adur et al.

24. Rosenbaum applies as above, teaching the use of maleic anhydride-modified polyolefin tie layers (col. 9 line 65-col. 10 line 4) but failing to specify a blend of a modified polyethylene copolymer with a polyolefin polymer. Adur teaches adhesive blends of grafted polyethylene homopolymers or copolymers, LDPE or LLDPE, and a poly(α-olefin), where the blends have improved adhesive strength with both polyolefins and polar substrates (col. 1 lines 36-56; col. 2 lines 4-10). The adhesives can be applied to substrates and co-extruded to form a number of articles (col. 1 lines 57-68). Examples of specific composites are listed, including polyolefin/adhesive/nylon,

polyolefin/adhesive/EVOH, and polyolefin/adhesive/polyester (col. 4 lines 15-27). Maleic anhydride is noted as a preferred modifying monomer (col. 2 lines 49-65; examples 40-41, at least). Therefore, it is the examiner's position that it would have been prima facie obvious to use the adhesive blend of Adur's teaching in the composite of Rosenbaum's invention to improve the adhesive strength between the polyolefin and polar substrate.

25. Claims 11-13 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piper et al. in view of Adur et al.

26. Piper applies as above, teaching the use of anhydride-modified polyolefin tie layers (examples) but failing to specify a blend of a modified polyethylene copolymer with a polyolefin polymer. Adur teaches adhesive blends of grafted polyethylene homopolymers or copolymers, LDPE or LLDPE, and a poly(α-olefin), where the blends have improved adhesive strength with both polyolefins and polar substrates (col. 1 lines 36-56; col. 2 lines 4-10). The adhesives can be applied to substrates and co-extruded to form a number of articles (col. 1 lines 57-68). Examples of specific composites are listed, including polyolefin/adhesive/nylon, polyolefin/adhesive/EVOH, and polyolefin/adhesive/polyester (col. 4 lines 15-27). Maleic anhydride is noted as a preferred modifying monomer (col. 2 lines 49-65; examples 40-41, at least). Therefore, it is the examiner's position that it would have been prima facie obvious to use the adhesive blend of Adur's teaching in the composite of Piper's invention to improve the adhesive strength between the polyolefin and polar substrate.

27. Claims 11-13, 22-24, 32-34, 42-44, and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Small, Jr. et al. in view of Adur et al.

28. Small, Jr. applies as above, teaching the use of modified polyolefin tie layers (examples) but failing to specify a blend of a modified polyethylene copolymer with a polyolefin polymer. Adur teaches adhesive blends of grafted polyethylene homopolymers or copolymers, LDPE or LLDPE, and a poly(α-olefin), where the blends have improved adhesive strength with both polyolefins and polar substrates (col. 1 lines 36-56; col. 2 lines 4-10). The adhesives can be applied to substrates and co-extruded to form a number of articles (col. 1 lines 57-68). Examples of specific composites are listed, including polyolefin/adhesive/nylon, polyolefin/adhesive/EVOH, and polyolefin/adhesive/polyester (col. 4 lines 15-27). Maleic anhydride is noted as a preferred modifying monomer (col. 2 lines 49-65; examples 40-41, at least). Therefore, it is the examiner's position that it would have been prima facie obvious to use the adhesive blend of Adur's teaching in the composite of Small, Jr.'s invention to improve the adhesive strength between the polyolefin and polar substrate.

29. Claims 11-13, 22-24, 32-34, 42-44, and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shang et al. in view of Small, Jr. et al. as applied to claims 10, 14-21, 25-31, 35-41, and 45 above, and further in view of Adur et al.

30. Shang and Small, Jr. apply as above, teaching the use of modified polyolefin tie layers (Small, Jr. examples) but failing to specify a blend of a modified polyethylene copolymer with a polyolefin polymer. Adur teaches adhesive blends of grafted polyethylene homopolymers or copolymers, LDPE or LLDPE, and a poly(α-olefin), where the blends have improved adhesive strength with both polyolefins and polar substrates (col. 1 lines 36-56; col. 2 lines 4-10). The adhesives can be applied to substrates and co-extruded to form a number of articles (col. 1 lines 57-68). Examples of specific composites are listed, including polyolefin/adhesive/nylon, polyolefin/adhesive/EVOH, and polyolefin/adhesive/polyester (col. 4 lines 15-27). Maleic anhydride is noted as a preferred modifying monomer (col. 2 lines 49-65; examples 40-41, at least). Therefore, it is the examiner's position that it would have been prima facie obvious to use the adhesive blend of Adur's teaching in the composite of Shang and Small, Jr. to improve the adhesive strength between the polyolefin and polar substrate.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie D. Bissett whose telephone number is (703) 308-6539. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (703) 308-2462. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

mdb
March 6, 2003

James J. Seidleck
Supervisory Patent Examiner
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